

Notice of Allowability

Application No.

10/748,096

Examiner

Matthew L. Fedowitz

Applicant(s)

MADHAVI ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to September 13, 2005.
2. ☒ The allowed claim(s) is/are 1,3-6,8-12,14-16,19,20,23 and 24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 1/24/2005
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DETAILED ACTION

During an interview with Jerry Mueller on September 30, 2005 and October 3, 2003 an agreement was reached where claims 10 and 24 were to be amended and is discussed below. The amendments to claims 10 and 24 were a result of questions relating to definiteness of claim language under 35 U.S.C. §112 Second Paragraph. In response to these questions, Mr. Mueller suggested claim language that traversed the Examiner's 35 U.S.C. §112 Second Paragraph questions in a Jepson style claim format.

The arguments filed September 13, 2005 have been received, entered and carefully considered.

- A. Claims 1, 3, 6, 8, 10 and 14 have been amended.
- B. Claims 2, 7, 13, 17, 18, 21 and 22 have been cancelled.
- C. Comments regarding the Office Action have been provided drawn to:
 - 1. Applicant's comments regarding the claim rejections under 35 U.S.C. §103 have been considered and are persuasive.
- D. Claims 1, 3-6, 8-12, 14-16, 19-20 and 23-24 are allowable.

Claim Rejections - 35 USC § 103

Applicant's comments and amendments regarding the claim rejections under 35 U.S.C. §103 have been considered and are persuasive in regard to claims 1-11, 13-20, 26-28 and 31.

Allowable Subject Matter

Claims 1, 3-6, 8-12, 14-16, 19-20 and 23-24 are allowable and are directed to allowable compositions and methods for preparing a water-dispersible, freeze-dried bioavailable complex

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of coenzyme Q-10 and one or more α -, β - or γ -cyclodextrin. The applicant's arguments and amendments presented in the reply dated September 13, 2005 and during the interview on September 30, 2005 are found to be persuasive in regard to claims 1, 3-6, 8-12, 14-16, 19-20 and 23-24. Claims 1, 3-6, 8-12, 14-16, 19-20 and 23-24 are found to be allowable because the claimed subject matter is not taught nor fairly suggested in the prior art. With regard to the compositions and methods claimed, the applicant's claim requirements to specific molar ratios in the final composition, and a step where coenzyme Q10 is added to cyclodextrin at room temperature followed by refrigeration distinguishes the applicant's claims from the prior art.

The closest prior art to the composition and method claims is found in Iijima et al. where coenzyme Q-10 and methylated β -cyclodextrin compositions are disclosed. The divergent factor between this reference and the applicant's claims are that the applicant requires specific molar ratios in the final composition, and a step where coenzyme Q10 is added to cyclodextrin at room temperature followed by refrigeration in the methods.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to the applicant, an amendment may be filed as provided by 37 CR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1. In claim 10, the phrase "A method for administering to an animal a bioavailable coenzyme Q-10 complex, which comprises the steps of: " has been changed. The claim should read as follows: --"In a method for administering to an animal in need thereof a bioavailable

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coenzyme Q-10 complex, said coenzyme Q-10 being useful for treating disease conditions comprising cardiovascular disease, periodontal disease, high blood pressure, Parkinson's disease, skin care, and oral health care, which comprises the steps of: "--

2. In claim 10, the phrase "administering said complex to an animal " has been changed.

The claim should read as follows: --"administering said complex to said animal"--.

3. In claim 24, the phrase "A method for administering to an animal a bioavailable coenzyme Q-10 complex, which comprises the steps of: " has been changed. The claim should read as follows: --"In a method for administering to an animal in need thereof a bioavailable coenzyme Q-10 complex, said coenzyme Q-10 being useful for treating disease conditions comprising cardiovascular disease, periodontal disease, high blood pressure, Parkinson's disease, skin care, and oral health care, which comprises the steps of:"--

4. In claim 24, the phrase "administering said complex to an animal " has been changed.

The claim should read as follows: --"administering said complex to said animal"--.

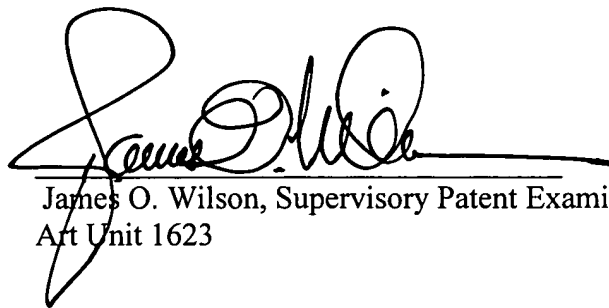
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105. If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., Esq.

A handwritten signature in black ink, appearing to read "James O. Wilson", is written over a horizontal line. The signature is stylized with large loops and a long horizontal stroke extending to the right.

James O. Wilson, Supervisory Patent Examiner
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